

healthy cells by immediately applying the corrective voltages at the onset of precursor lesion symptoms.

The third grouping is basically the method of treating herpes virus lesions and the fourth is the apparatus used.

In all methods, the underlying concept is to act upon the individual cells that are infected or threatened with infection rather than working through the peripheral nervous system or the somatic system in general to alleviate pain and discomfort of the patient. A number of systems for relief of pain have been in existence for some years and are generally categorized as TENS units which reduce the trauma of the infection and thus perhaps indirectly promote healing. These systems generally involve placing of electrodes within selected dermatomes or other nerve ganglia systems and involve usually a detailed diagramming of the human body enumerating the various nerve ending points to be utilized for treatment of specific areas of the body. This method is typified applicant believes, by the patent '148 to Diethelm and while quite successful apparently in relieving patient discomfort, the healing of lesions is incidental and there is no effort or teaching to inhibit development of the lesions before they occur in references of this type.

A second major type of attempt to cure herpes virus infections is of course, the electrochemical as typified by Swartz '128. In Swartz and other references of this type, an electrical field or current is used to facilitate the release of chemical substances that can attack and kill the virus infecting the patient. Thus, in Swartz, methylene blue, light and electricity are used in combination to release singlet oxygen in

various forms to attack the virus itself. The incidental use of a DC voltage in Swartz for the various time periods specified has nothing to do with changing the electrical state of the infected cell, but rather is used to facilitate the chemical attack on the virus lesion and the virus associated therewith.

Accordingly, the rejection of claims 4, 6, 9-14 as being anticipated under Sec. 102(b) by Diethelm is respectfully traversed. Claim 4, as now amended, clearly requires the application of the low DC voltage to the skin immediately adjacent the symptom site so as to affect the protein envelope of the herpes virus infected cell itself as well as the uninfected cells that are causing the virus symptom at the skin surface. Claim 4 as now amended requires not only the application of the voltage to the skin, but also the breaking up of the structure of the virus core and the stimulation and restoring of the infected cell capacitance to its normal functioning levels so as to cause the virus to retreat to its own original dormant state within its own protein cell. This action it is believed is quite different from that taught by Diethelm. Diethelm teaches working through the peripheral nervous system to alleviate the trauma and pain associated with the herpes virus lesion and to incidentally promote healing which generally occurs when the trauma to the nervous system is removed. Claim 6 adds the specific regimen recommended by applicant of 2 to 15 second applications hourly for at least the first 8 hours after onset of the tingling symptom. Diethelm discloses a pulsed DC having a frequency of 5 to 150 hertz which applicant submits is more than a pulsed DC. The Diethelm pulses have a 2 milisecond duration with a current

of 5 to 100 miliamps and the treatment cycle is defined as a 20 minute treatment administered 3 times a day. This treatment regimen, even if applied in the same manner as applicant, which it is not, is a totally different regimen, quite likely because it is intended to perform a different function in the human body.

Swartz exposed the virus for a short time frame of 60 to 300 seconds, but the treatments disclosed by Swartz were done in vitro, and there is no regimen disclosed for application to the human body. The whole teaching of Swartz is directed toward the sterilization of herpes virus by the combination of methylene blue, light and electricity which is dependent apparently on super-oxide free radical formations which chemically or pharmacologically attack the virus.

Claims 12-15 and 17 as now amended are directed to the prevention of the development of lesions by applying the DC electric field directly to the cell being attacked by the virus to assist the cell in fighting off the virus and to restore it to its full healthy state so that it is able to repel the virus attack. Claim 12 as amended requires the application of voltage to the body skin directly adjacent to the precursor symptom so that the effect can be localized to the cells involved rather than indirectly through the peripheral nervous system of the body. Again, the specific regimen is spelled out in the claims dependent from claim 12. The Diethelm Nicad batteries are used to power the apparatus to create the square wave pulses and are not used to apply a DC directly to the body or the infected cells. It is respectfully submitted there is no teaching in Diethelm nor the other art to apply the treatment before lesions

appear. Diethelm is directed to relieving the pain of the lesions and Swartz is intent on killing the virus in the lesions. Applicant prefers to prevent the formation of the lesions. It is therefore respectfully submitted that Diethelm does not teach the method of applicant as claimed in claims 4, 10-12, 14, 15, 18, 20 and 23.

The rejection of claims 24-26 under 35 USC 102(b) as being anticipated by Clark is respectfully traversed. Admittedly, Clark shows a small apparently hand-held device containing a battery, but that is about as close as he comes. The electrodes "o" are freely movable electrodes that can be positioned at any desired spacing and location on the body. Also, the battery is connected through an induction coil e-e and spark gap arrangement to actually apply an AC or pulsed DC to the body of the patient. It is respectfully submitted that Clark does not show "a pair of probes extending from one side of the housing spaced apart from three-quarters to one-and-a-half-inches" nor does the cited reference teach the direct connection of the applicator metal caps at the ends of the probe to the battery without any switch or other device so that the instrument can be quickly and directly applied to the skin of the patient about the point of attack of the virus.

The rejection of claims 6, 13, 15, 17, 18 and 21 under 35 USC 103 as being obvious over Diethelm in view of Swartz is respectfully traversed. As the Examiner notes, Diethelm does not show the short duration repetitive regimen set forth in the claims. It is believed that the application of a DC field to the human body for very short durations at regular intervals over an

extended period is not obvious from Swartz or any other reference showing a short time cycle. Swartz shows a one to three minute application of current, light and chemical directly to an invitro virus culture to "inactivate" the virus. Application to the skin will "logically" take longer to inactivate virus infected cells. Generally speaking, the normal individual's reaction is that if one second is good two is better and ten is much better. The normal and obvious tendency is to increase the treatment time as much as possible without damaging the human tissue, hence Diethelm's 20 minute treatment period. Applicant respectfully submits it would not have been obvious to one skilled in the art given Diethelm and Swartz to prescribe a 15 second treatment once an hour. Applicant's regimen is directly opposite, namely a very short duration (2-20 sec.) application of the electric field, but on a regular periodic basis over an extended time period, preferably before appearance of any lesions. Even after appearance of lesions, the regimen is still a very short duration at periodic intervals over an extended time period.

The rest of the art cited by the Examiner is noted. It is directed to 1) sensory nervous systems (with at least one of them being directed to acupuncture point manipulation); 2) DC type high voltage devices for applying a field to accelerate bone healing. Foxue for instance, is definitely of this type.

The disclosure in Diethelm of the placement of electrodes on the head at a relatively close distance still is not anticipatory of applicants' claim 10. The whole tenor and purpose of the placement in Diethelm is to place them at opposite ends of the dermatome. On the head the ends of the dermatome

happen to be fairly close together, whereas on other parts of the body, they may be quite a distance away. Also, it would appear to applicant that on the average human skull the spacing between the two ends of the dermatome would be on the order of two to three inches which is outside the spacing specified in applicants' claims, even if Diethelm could be said to teach the placement in Applicant's manner for individual cell manipulation.

Finally, it is respectfully submitted that none of the references alone or in combination teach the concept of direct cell manipulation by electrical field applied in close proximity to the cell to affect the electrical state of the cell so as to assist the cell in fighting off a viral attack at the very outset of attack symptoms.

In view of the foregoing amendments and remarks, reconsideration and allowance are earnestly solicited.

Respectfully submitted,

WALL and ROEHRIG

By 
Robert O. Wright, Reg. No. 17,097

ROW/pp
710 Hills Building
Syracuse, NY 13202
315/422-7383